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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/901,983	07/10/2001	S. Indiran Pather	CIMA 3.0-036	7927

530 7590 09/25/2002

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EXAMINER

AZPURU, CARLOS A

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 09/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/901,983

Applicant(s)

Pather et al

Examiner

Carlos Azpuru

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4-6 6) ☐ Other:

DETAILED ACTION

Receipt is acknowledged of the information disclosure statements filed 12/07/01, 03/19/02, and 06/03/02. A preliminary amendment was filed 07/16/02.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al.

Zhang et al disclose a formulation and method for oral transmucosal delivery of a pharmaceutical (see Abstract). The formulation may contain a pH segregation so that the pH in the particles is optimized so that the drug is in ionized (higher dissolution), while the rest of the formulation is pH adjusted for higher absorption (see col. 7, lines 65 et seq; col. 8, lines 1-16). This adjustment utilizes either acids or bases depending on whether the drug is basic or acidic, respectively. Further, while in storage, the pharmaceutical agent and buffer are separated (see claim 5). Further, the drug exists in a microenvironment which promotes the stability of the drug, while the rest of the formulation promotes absorption. The absorption may occur by adjustments in the environmental pH (see col. 9, lines 35-36. Drugs for incorporation into this partitioned pharmaceutical are listed at col. 9, lines through col. 11, lines 1-24. The formulation may

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be formulated as a patch, lozenge, lollipop, or chewing gum. Controlled release is achieved by manipulating the drug dissolution and disintegration rate of the formulation (see col. 8, lines 60-62). The instant method of transmucosally delivering a pharmaceutical and transmucosal pharmaceutical itself would have been well within the skill of the ordinary practitioner given the claims of Zhang et al which deliver an agent to a desired site by adjusting the local environment of the active ingredient to promote dissolution within the particle, and then adjusting the formulation of the rest of the formulation to promote absorption. Those of ordinary skill would expect similar therapeutic results from the instant method and formulation given the disclosure of Zhang et al. Therefore, the instant invention would have been obvious to those of ordinary skill in the art given the disclosure of Zhang et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is 703/308-0237. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

ca
September 24, 2002


CARLOS AZPURU
PRIMARY EXAMINER
GROUP 1500